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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/902,692	07/30/1997	WILLIAM J. REA	16715CIP	1465

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/902,692	REA ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 49-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 49-66 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O

1. In view of the Brief filed on 1/28/2003, PROSECUTION IS HEREBY REOPENED. As set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Claims 49-66 are under consideration.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 65,66 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

There is no support in the specification as originally filed for the method of claim 65 which recites "which includes at least some normal T and B lymphocytes". There is no written descritpion of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

Regarding applicants comments, there is no support in the specification as originally filed for the method of claim 65 which recites "which includes at least some normal T and B lymphocytes". There is no disclosure of said limitation in the method disclosed in pages 8- 10 of the specification.

5. Claims 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 is indefinite in the recitation of "normal T and B lymphocytes" because it is unclear what this term means or encompasses. It is unclear as to what parameters distinguish a normal lymphocyte from an abnormal lymphocyte. The meaning of said term is not disclosed in the specification and it has no art recognized meaning.

Regarding the Scholes declaration, said declaration does not clarify what "normal T and B lymphocytes" means or encompasses. In fact, said declaration actually indicates that said term could potentially be interpreted in a variety of different ways (eg. normal in appearance versus normal in function). Furthermore, the claims to do not recite the limitation "normal functioning". Even if the claims did recite said limitation, it would be unclear as to what "normal functioning" means or encompasses. For example, what parameters are encompassed by "normal functioning" versus "abnormal functioning" of T and B cells.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 49-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youdim et al. in view of Warren (US Patent 4,435,384), Goust et al. (US Patent 4,001,080) and Lane et al.

Youdim et al. teach the treatment of "environmentally sensitive patients" with transfer factor (see entire document). The transfer factor is prepared from lysed leukocytes (see page 56, first column). The "environmentally sensitive patients" would be encompassed by the term "chemically sensitive individual". Youdim et al. do not teach that the transfer factor was produced from autologous blood cells as per claim the

claimed invention. Warren teaches that transfer factor can be obtained from the lymphocytes of any individual as long the donor has no history of recurrent infection by herpes virus (see column 2). Therefore a routineer would have used any source of lymphocytes, including autologous, for preparing transfer factor for use in the method taught by Youdim et al. Youdim et al. do not teach that the transfer factor was produced using the particular steps recited in the claimed method. Goust et al. teach that transfer factor can be produced by culturing/propagating PBL for various periods of time in vitro followed by lysis of said cells to produce a lysate containing transfer factor (see Example 3, columns 5-6). The PBL are contained in a blood sample. Goust et al. teaches use of PBL (which contain T and B lymphocytes) indicating that said cells were isolated form peripheral blood (which contains leukocytes per se). Warren teaches the use of heparinized tubes to collect the blood sample. The use of commercially available density gradients such as HYPAQUE-FICOLL (a well known commercially available version of the agent recited in claim 51/claim 60 part(b)) using the steps recited in the claims to isolate/separate lymphocytes is well known in the art (for example see Lane et al., page 66.2). The culture of lymphocytes at 37 degrees C is standard operating procedure (for example Warren teaches 37 degree incubation of lymphocytes (see column 2)). Goust et al. teach use of bovine calf serum in the culture process (see Example 3, column 5 wherein fetal calf serum is encompassed by the term bovine calf serum). Goust et al. teach that new media is added as needed (see Example 3, column 5). While Goust et al. teach that the lysate is obtained via freezing and thawing cells, Goust et al. teach that the transfer factor can be produced by disrupting the cells wherein sonication is an art known procedure for disrupting cells. Warren teaches that transfer factor can be produced by a variety of different methods. Centrifugation and washing of cultured cells are routine tissue culture steps for cells grown in suspension. Youdim et al. teaches subcutaneous administration of transfer factor (see page 56, column 2). Youdim et al. teaches multiple administration of transfer factor (see page 56, column 2). Youdim et al. teaches that skin testing (eg. DTH) can be used to measure the response to transfer factor. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Youdim et al. teach the treatment of "environmentally sensitive patients" with transfer factor, Warren teaches that transfer factor can be obtained from

the lymphocytes of any individual as long as the donor has no history of recurrent infection by herpes virus, Goust et al. teach that transfer factor can be produced by culturing/propagating PBL for various period of time in vitro following by lysis of said cells to produce a lysate containing transfer factor and the particular steps recited in the clams are art known steps used in the in vitro isolation or culture of lymphocytes. One of ordinary skill in the art would have been motivated to do the aformentioned because Youdim et al. teach the treatment of "environmentally sensitive patients" with transfer factor, Warren teaches that transfer factor can be obtained from the lymphocytes of any individual as long as the donor has no history of recurrent infection by herpes virus, and the transfer factor could have been produced using any art known method.

Regarding applicants comments about Warren, Warren does not teach that the transfer factor is obtained from pooled donors. Warren teaches that the transfer factor can be obtained from "a donor" (see column 2, lines 46-50). Similarly, Goust et al. teach use of lymphocytes from a single donor to produce transfer factor (see column 5, lines 25-30). In view of the fact that the a single donor is used and Warren discloses that the donor has no history of recurrent herpes virus, then use of autologous donor cells would have been obvious as one of the choices encompassed by the teachings of Warren. Regarding applicants comments about Warren and the methods used to produce transfer factor, Goust et al. teach production of transfer factor using cultured lymphocytes. Regarding applicants comments about Warren and propagation, Goust et al. teach production of transfer factor using cultured/propagated lymphocytes wherein the cells are cultured in vitro for extended periods of time. Regarding applicants comments about the term "propagation", Goust et al. teach a method that is encompassed by the term "propagation" in view of the particular definition of the word as per argued by applicant in page 18-19 of the filed Brief. There is currently no claim under consideration which recites any particular length of culture time. Regarding applicants comment about growth medium, Goust et al. teach transfer factor produced by propagation of lymphocytes in vitro with cell growth media which includes fetal calf serum (see Example 3).

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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